

**PATENT APPLICATION TRANSMITTAL LETTER**  
(Small Entity)

Docket No.  
**MED-00802/29**

TO THE ASSISTANT COMMISSIONER FOR PATENTS

Transmitted herewith for filing under 35 U.S.C. 111 and 37 C.F.R. 1.53 is the patent application of:

**Michael A. Masini**

For: **MODULAR ACETABULAR RECONSTRUCTION PLATE**

Enclosed are:

- ☒ Certificate of Mailing with Express Mail Mailing Label No. **EE480942457US**
- ☒ **Four (4) formal** sheets of drawings.
- ☐ A certified copy of a \_\_\_\_\_ application.
- ☒ Declaration ☒ Signed. ☐ Unsigned.
- ☒ Power of Attorney
- ☐ Information Disclosure Statement
- ☐ Preliminary Amendment
- ☒ **One** Verified Statement(s) to Establish Small Entity Status Under 37 C.F.R. 1.9 and 1.27.
- ☐ Other:

**CLAIMS AS FILED**

For	#Filed	#Allowed	#Extra	Rate	Fee
Total Claims	15	- 20 =	0	x \$11.00	\$0.00
Indep. Claims	2	- 3 =	0	x \$41.00	\$0.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00
BASIC FEE					\$395.00
TOTAL FILING FEE					\$395.00

- ☒ A check in the amount of **\$395.00** to cover the filing fee is enclosed.
- ☒ The Commissioner is hereby authorized to charge and credit Deposit Account No. **07-1180** as described below. A duplicate copy of this sheet is enclosed.
  - ☐ Charge the amount of \_\_\_\_\_ as filing fee.
  - ☒ Credit any overpayment.
  - ☒ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
  - ☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).

Dated: **July 27, 1998**

*Signature*

**John G. Posa**  
Reg. No. 37,424  
Gifford, Krass et al  
280 N. Old Woodward Ave., Suite 400  
Birmingham, MI 48009  
734/913-9300

cc:

## MODULAR ACETABULAR RECONSTRUCTION PLATE

### Reference to Related Application

This application claims priority of U.S. provisional application Serial No. 60/054,259, filed July 30, 1997, the entire contents of which are incorporated herein by reference.

5

### Field of the Invention

This invention relates generally to orthopedics and, in particular, to a versatile reconstruction system associated with acetabular prosthetics.

### Background of the Invention

10

Especially in the case of revision surgical procedures wherein the pelvis has been severely compromised or deteriorated, it is known to use support structures to receive an acetabular prosthetic device.

15

One such structure is disclosed in U.S. Patent No, 5,314,490 to Wagner et al, entitled OUTER CUP FOR AN ARTIFICIAL HIP JOINT SOCKET. According to this patent, an artificial hip joint socket for fastening to a pelvic bone includes a metallic outer cup forming a concavity for receiving a hip, which terminates in an equatorial edge to which supporting flaps are fastened. The flaps include holes to receive bone screws and have preset lines of grooves to enabling preferential bending to provide conformance with the pelvic region surrounding the procedure. The problem with

this particular configuration, and others like it, is that, even with the grooves affording preferential bending, the flaps are not sufficiently malleable or adjustable in multiple dimensions to permit conformance to surrounding bone in all  
5 situations.

### Summary of the Invention

The present invention addresses a deficiency in the prior art by providing a more flexible, modular acetabular reconstruction plate and system of installation incorporating  
10 other advantages.

Apparatus according to the invention includes a generally cup-shaped portion having a peripheral rim and back surface adapted for fixation within a human pelvis, and one or more malleable extension arms connected to the rim of the cup-  
15 shaped portion. In the preferred embodiment, each malleable extension arm includes one or more apertured sections spaced apart from one another by a necked-down section, thus enabling each arm to be manipulated in three dimensions, as desired, so as to assume a shape in intimate conformity with surrounding  
20 bone.

To enhance installational stability, modular acetabular reconstruction apparatus according to the invention preferably includes at least one malleable extension arm adapted for overlying contact with the ilium of a human  
25 pelvis. One malleable extension arm adapted for overlying contact with the ischium of a human pelvis would also be

advantageous. Laterally or medially oriented arms may further be provided, and in the event of pairs of arms which are sufficiently closely spaced, apart, malleable apertured bridge elements may further be provided between adjacent arms.

5           The back surface of the generally cup-shaped portion may be adapted for a cemented or a non-cemented interface within a human pelvis; as such, the back surface may be adapted for porous bone in-growth.

10           The invention further includes a method of treating a human acetabulum, wherein each malleable extension arm is manipulated in multiple dimensions, as required, so that each arm is in intimate physical conformity with the surrounding bone prior to fastening and fixation. Various bending tools and techniques are also disclosed in the accompanying detailed  
15 description and drawings which follow.

#### Brief Description of the Drawings

FIGURE 1 is a lateral view of the acetabular area of a human pelvic region, depicted in conjunction with apparatus according to the invention featuring one or more outwardly  
20 extending arms with screw-receiving apertured sections between necked-down sections;

FIGURE 2A shows how the outwardly extending arms of the invention may be tilted relative to one another to achieve improved conformity with surrounding bone;

25           FIGURE 2B shows how the outwardly extending arms of the invention may be angled to relative to one another;

FIGURE 2C shows how the outwardly extending arms of the invention may also be bent toward and away from one another;

FIGURES 3A-3C illustrate alternative load-bearing  
5 insert configurations according to the invention;

FIGURE 4 is a diagram of tools according to the invention which may be used to more efficiently bend the extension arms;

FIGURE 5A begins a series of drawing which  
10 illustrate ways in which an inventive bending tool may be applied to adjust the extension arms. In particular, Figure 5A illustrates a first and second tools inserted into adjacent apertures to interact above the plane of the extension arm;

FIGURE 5B illustrates how alternative first and  
15 second tools are inserted into adjacent aperture to interact below the plane of the extension arm;

FIGURE 5C shows how a portion of each screw-receiving hole may be non-round with a remaining portion of the hole being round or adapted for better conformance with  
20 the shaft or head of the particular fastener being used; and

FIGURE 5D depicts an alternative bending tool including inner surfaces which conform to the outer dimensions of the elements forming the extension plates.

#### Detailed Description of the Invention

25 Now making reference to the accompanying drawings, Figure 1 is a lateral view of the acetabular area of a pelvic

region to which this invention applies. The apparatus includes a central plate portion 20 which is preferably in the form of a hemispherical socket or symmetrical cup. The plate 20 need not assume such a shape in all circumstances, however, 5 as shown by broken line 22, which is used to indicate that, in situations where the bone itself is relieved relative to the acetabulum, the plate 20 may be relieved as well.

The plate 20 preferably includes a plurality of apertures 24 to receive bone screws and/or to provide a means 10 for cement interdigitation. The plate further includes an outer edge 21 to which there is attached a plurality of malleable extension arms such as 10, 12 and 14. Although there may be more or fewer such arms than those depicted, their positioning is chosen to correspond to surrounding areas 15 of "good bone" to better ensure stable anchoring.

A preferred embodiment includes two upwardly oriented malleable extension arms 12 and 14, and at least one lower arm 10, though others, such as 16, may be added as desired. An optional bridge element 18 between the members 12 20 and 14 may also be provided.

In contrast to prior-art devices, the arms 10, 12 and 14 preferably feature a series of sequential screw-receiving apertured sections such as 26 and 28, which are connected by necked-down sections such as 27, thereby enabling 25 the apertured sections to be bent relative to one another in multiple dimensions.

For example, Figure 2A shows how the sections 26 and

28 may be tilted relative to one another; Figure 2B shows how the plates may be angled to relative to one another and, Figure 2C illustrates with arrows how the plates 26 and 28 may also be bent toward and away from one another within the same  
5 plane.

Overall, owing to the shaped geometry of the extension arms, the apertured sections may be bent using one, more, or all of the degrees of freedom just described, thereby facilitating conformity to the surrounding bone in three  
10 dimensions. Another feature of preferred geometry is that one or more sections of an extension arm which are not required may easily be clipped off at an appropriate necked-down section.

According to a method of installing the inventive  
15 reconstruction system, a first step includes preparation of the acetabulum, as by reaming, to create a suitable bed such as a hemispherical cavity. Bone graft may be used to augment any deficient portions, using supplemental fixation as necessary. The central plate portion 20 is then placed into  
20 the prepared area, and contoured as necessary in accordance with surrounding bone, and then fixed it into place with bone screws, using either the holes in the plate 20 or those of the extension arms, depending optimum initial conformance. After stabilizing the device, the extension arms may then be bent as  
25 necessary to conform to the remaining bone and held into place at that point. Alternatively, one or more of the extension arms may be contoured prior to placement of the cup portion

within the acetabulum.

Once installed, the central plate portion 20 is configured to receive a bearing surface, which may be constructed of polyethylene, ceramic or other material, as appropriate. According to another aspect of the invention, means may be provided for at least temporarily installing the bearing surface into the plate 20. In this way, the bearing surface may be temporarily removed for the introduction of cement.

In addition, the bending of the extension arms may be carried out partially or completely during a trial reduction. In this case, the bearing surface may be clipped into the plate 20, and, with the plate 20 including the bearing surface generally positioned into the acetabulum, a trial reduction may be performed. Assuming a successful trial, one or more screws may be used to hold the assembly in place, after which, having dislocated the joint, additional screws may be added, with the bearing surface being removed to gain access to the holes at the bottom portion of the plate 20, as required. It should be noted that the invention is applicable to both cemented and cementless configurations, such that, in accordance with the latter, a bone in-growth surface may be provided on at least the back side of the plate 20.

Figures 3A-3C illustrate alternative load-bearing insert configurations according to the invention. Figure 3A illustrates an insert encompassing a full perimetry of the



cup-shaped portion of the plate, whereas Figures 3B and 3C illustrate partial inserts having differently styled cut-out portions according to the extent of the required construction of other aspects of the surgical procedure. In the event that  
5 a slight repositioning of the bearing surface is to be made within the central plate, the bearing surface may be eccentrically formed along one or more dimensions, thereby enabling the insert to be installed and rocked or rotated until the correct positioning of the insert is established.

10 Figure 4 shows tools according to the invention which may be used to more efficiently bend the extension arms. Tools such as 42 and 44, for example, may be inserted into corresponding apertured sections and moved relative to one another to bend the extension arm. Protrusions 45 may be  
15 provided as points of leverage for more accurate manipulations. Tools such as 46 and 48 may be used in the event that insertion through a hole is desirable prior to bending.

Figure 5 illustrates ways in which such benders  
20 would be applied. In Figure 5A, a first tool 50 is inserted into one aperture and a second tool 52 is inserted into an adjacent aperture, with the protrusions between the two tools establishing a close interface 54 above the plane of the extension arm itself. These two facing protrusions may or may  
25 not touch, depending on the circumstances, having positioned the tools so as to create a desired bend.

The handle portions of the two tools 50 and 52 are

then, for the most part, pressed toward one another causing the two holes to flip up relative to each other. Figure 5B uses tools such as 46 and 48, which are inserted through adjacent holes such that the protrusions 56 and 58 are  
5 actually underneath the plane of the extension arms and, with the handles (not shown) pulled apart the apertured sections may be bent downwardly and away from one another.

As a further alternative, the aperture itself need not be round, but may be non-round, such as oval-shaped,  
10 hexagonal, octagonal, and so forth, enabling the end of the tool such as 48 shown in Figure 4 to be similarly shaped, thereby preventing rotational movement during the bending process. As a further alternative, a portion of each hole may be non-round as disclosed above with a remaining portion of  
15 the hole being round or adapted for better conformance with the shaft or head of the screw being used, as shown in Figure 5C. As shown in Figure 5D, as an alternative to having a tool which conforms to the aperture, the tool may be made larger to include inner surfaces which conform to the outer dimensions  
20 of the elements forming the extension plates, as shown in Figure 5D.

I claim:

1. Modular acetabular reconstruction apparatus,  
2 comprising:

a generally cup-shaped portion having a peripheral  
4 rim and back surface adapted for fixation within a human  
pelvis; and

6 one or malleable extension arms connected to the rim  
of the cup-shaped portion, each arm including one or more  
8 apertured sections spaced apart from one another by a necked-  
down section enabling each arm to be manipulated in three  
10 dimensions in intimate conformity with surrounding bone.

2. The modular acetabular reconstruction apparatus  
2 of claim 1, including:

at least one malleable extension arm adapted for  
4 overlying contact with the ilium of a human pelvis.

3. The modular acetabular reconstruction apparatus  
2 of claim 1, including:

at least one malleable extension arm adapted for  
4 overlying contact with the ischium of a human pelvis.

4. The modular acetabular reconstruction apparatus  
2 of claim 1, including:

two adjacent malleable extension arms adapted for  
4 overlying contact with the bone surrounding the acetabulum;  
and

6 an apertured bridge element between the two arms.

5. The modular acetabular reconstruction apparatus  
2 of claim 1, wherein the back surface of the generally cup-  
shaped portion is adapted for a non-cemented interface within  
4 a human pelvis.

6. The modular acetabular reconstruction apparatus  
2 of claim 4, wherein the non-cemented interface is configured  
for porous bone in-growth.

7. The modular acetabular reconstruction apparatus  
2 of claim 1, further including a bearing surface adapted for  
cementation within the cup-shaped portion.

8. The modular acetabular reconstruction apparatus  
2 of claim 1, further including a bearing surface adapted for  
cementless installation within the cup-shaped portion.

9. A method of treating a human acetabulum,  
2 comprising the steps of:

providing a prosthetic element having a generally  
4 cup-shaped portion back surface adapted for fixation within  
the acetabulum and a peripheral rim including one or malleable  
6 arms extending outwardly therefrom, each arm including one or  
more apertured sections spaced apart from one another by a  
8 necked-down section enabling each arm to be manipulated in  
three dimensions in intimate conformity with surrounding bone;

10 installing the cup-shaped portion such that the back  
surface thereof is in physical conformity with the acetabulum  
12 and the extension arms generally overly surrounding bone;  
bending each arm in multiple dimensions, as  
14 required, so that each arm is in intimate physical conformity  
with the surrounding bone; and  
16 fastening each arm to the surrounding bone, thereby  
stabilizing the position of the cup-shaped portion with the  
18 acetabulum.

10. The method of claim 9, wherein the step of  
2 bending each arm in multiple dimensions is carried out a part  
of a trial joint reduction.

11. The method of claim 9, wherein the step of  
2 bending each arm in multiple dimensions is carried out by  
applying a tool to adjacent apertured sections of a particular  
4 arm and manipulating the tools to bend the arm.

12. The method of claim 11, wherein each tool  
2 includes a distal end adapted for engagement with an aperture  
and a protrusion which interacts with the protrusion of the  
4 other tool to provide leverage during bending.

13. The method of claim 11, wherein:  
2 each apertured section includes an outer shape; and  
each tool includes a socket portion configured to

4 engage with the outer shape.

14. The method of claim 9, further including the  
2 steps of:

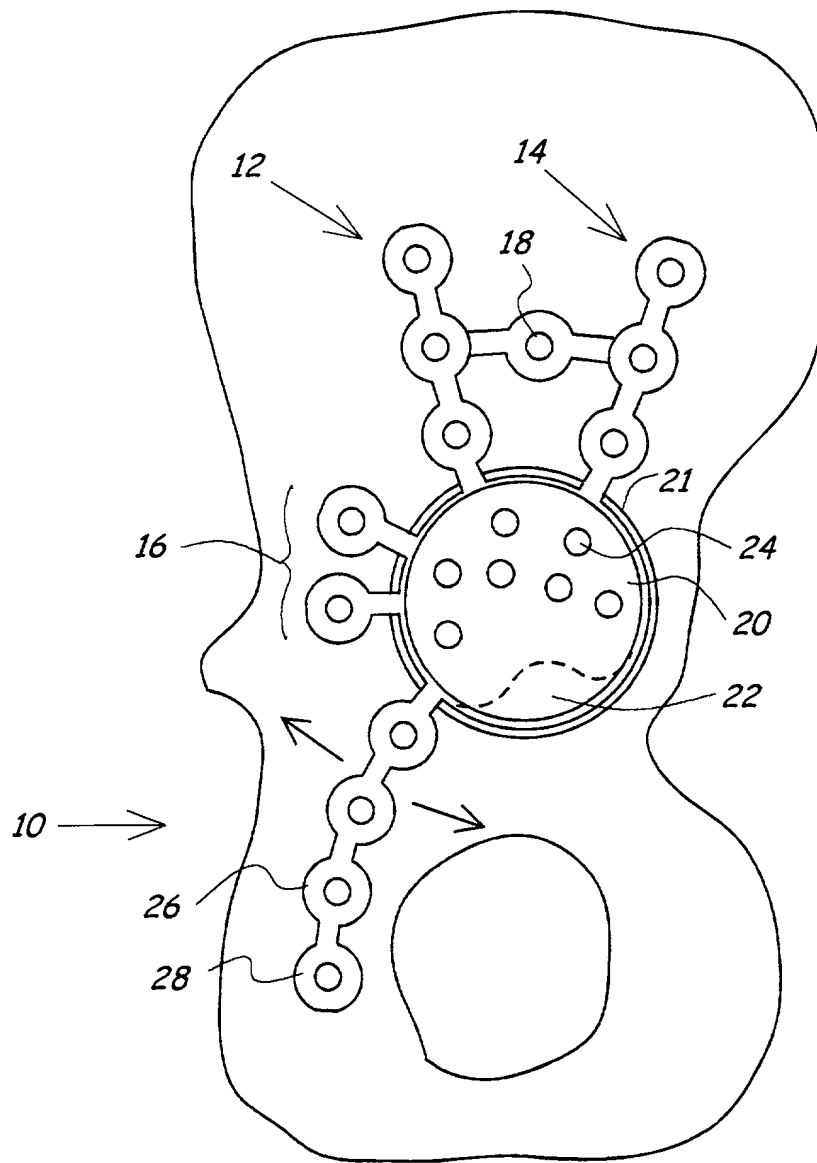
providing a bearing surface; and  
4 cementing the bearing surface into the cup-shaped  
portion.

15. The method of claim 9, further including the  
2 steps of:

providing a bearing surface; and  
4 installing the bearing surface into the cup-shaped  
portion without the use of cement.

Abstract of the Disclosure

Modular acetabular reconstruction apparatus includes a generally cup-shaped portion adapted for fixation within a human pelvis and one or malleable extension arms adjustable in multiple dimensions. Each arm preferably includes one or more apertured sections spaced apart from one another by a necked-down section enabling each arm to be manipulated in three dimensions for intimate physical conformity with surrounding bone. The back surface of the generally cup-shaped portion may be adapted for a cemented or a non-cemented interface within a human pelvis; as such, the back surface may be adapted for porous bone in-growth. According to a disclosed method, the step of bending each arm in multiple dimensions may be carried out a part of a trial joint reduction. Various bending tools and techniques are also set forth.



**Figure - 1**





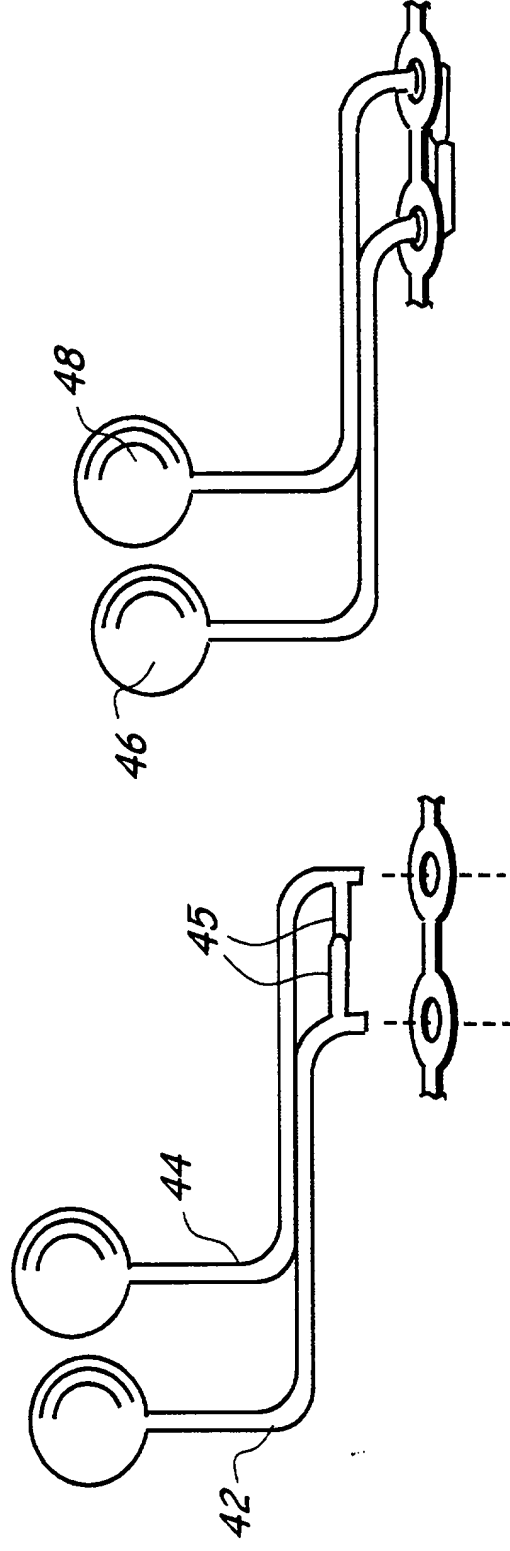


Figure - 4



**COMBINED DECLARATION, POWER OF ATTORNEY  
AND VERIFIED STATEMENT CLAIMING SMALL ENTITY STATUS**

As the below named inventor, I hereby declare my residence, post office address and citizenship are as stated below next to my name; and I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**MODULAR ACETABULAR RECONSTRUCTION PLATE**

the specification of which

- ☒ is attached hereto.
- ☐ was filed on \_\_\_\_\_ as ☐ Serial No. 0 / \_\_\_\_\_  
\_\_\_\_\_ or ☐ Express Mail No., as *Serial No. not yet known* \_\_\_\_\_  
\_\_\_\_\_ and was amended on \_\_\_\_\_ (if  
*applicable*).
- ☐ was described and claimed in PCT International Application No. \_\_\_\_\_  
\_\_\_\_\_ filed on \_\_\_\_\_ and as amended under PCT  
Article 19 on \_\_\_\_\_ (if any).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge to the duty to disclose information which is material to patentability as defined in 37, Code of Federal Regulations, §1.56(a). I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application on which priority is claimed:

**PRIOR FOREIGN APPLICATION(S)**

			Priority Claimed	
			Yes	No
_____ (Number)	_____ (Country)	_____ (Day/month/year filed)	<input type="checkbox"/>	<input type="checkbox"/>
_____ (Number)	_____ (Country)	_____ (Day/month/year filed)	<input type="checkbox"/>	<input type="checkbox"/>

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(App. Serial No.) (Filing date) (Status)  
(patented, pending, abandoned)

(App. Serial No.) (Filing date) (Status)  
(patented, pending, abandoned)

**CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)**

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

PROVISIONAL APPLICATION NUMBER

FILING DATE

60/054,259

July 30, 1997

And I hereby appoint Ernest I. Gifford, Reg. No. 20,644; Allen M. Krass, Reg. No. 18,277; Irvin I. Groh, Reg. No. 17,505; Douglas W. Sprinkle, Reg. No. 27,394; Thomas E. Anderson, Reg. No. 31,318; Ronald W. Citkowski, Reg. No. 34,732; Judith M. Riley, Reg. No. 30,311; Theresa A. Orr, Reg. No. 34,890; Douglas J. McEvoy, Reg. No. 34,385; Ellen S. Cogen, Reg. No. 38,109; Roberta J. Morris, Reg. No. 33,196; John G. Posa, Reg. No. 37,424; and Douglas L. Wathen, Reg. No. 41,369 as my attorneys, to prosecute this application and to transact all business in the United States Patent and Trademark Office connected therewith. Send all correspondence to:

John G. Posa, Esq.  
GIFFORD, KRASS, GROH, SPRINKLE,  
PATMORE, ANDERSON & CITKOWSKI, P.C.,  
280 N. Old Woodward Ave., Suite 400  
Birmingham, Michigan 48009  
Telephone (734) 913-9300

I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention described in the specification. I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a non-profit organization under 37 CFR 1.9(e). Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☒ no such persons, concern, or organization  
☐ persons, concerns or organizations listed below

FULL NAME \_\_\_\_\_

ADDRESS \_\_\_\_\_

☐ Individual ☐ Small Business Concern ☐ Non-Profit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon.

Full name of sole inventor MICHAEL A. MASINI

Inventor's signature 

Date 7/27/98 Country of Citizenship US

Residence Ann Arbor, Michigan

Post Office Address 2950 Hickory Lane, Ann Arbor, Michigan 48104